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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,773	11/04/2003	Hongming Chen	TPI5020USNP	5482

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EXAMINER	
HYUN, PAUL SANG HWA	
ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,773	CHEN ET AL.	
	Examiner	Art Unit	
	PAUL S. HYUN	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-22* is/are pending in the application.

4a) Of the above claim(s) *1-5 and 7-18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

REMARKS

Claims 1-5 and 7-22 remain pending with claims 1-5 and 7-18 being withdrawn for being drawn to a non-elected invention. No amendments were made.

It should be noted that the status of the previous Office action was erroneously indicated on the cover sheet. The previous Office action should not have been final. Therefore, the finality of the previous Office action has been withdrawn.

Despite Applicant's arguments, the art rejection cited in the previous Office action is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **19-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over McMahon et al. (US 6,004,967) in view of Lee et al. (US 2003/0230488 A1) as evidenced by www.wikipedia.com.

McMahon et al. disclose a method for determining the solubility of the pharmaceutical compound "A1" (see Table 1 in col. 19 for identity of A1) in various

excipients wherein the pharmaceutical preparation can comprise solids or non-aqueous liquid (see lines 6-48, col. 17 and Table 4 in col. 20). Specifically, Table 4 shows the solubility of compound A1 having concentration of 10 mg/mL in two different concentrations of polysorbate-80 excipient. Polysorbate-80 has viscosity ~300-500 cP (see wikipedia.com wherein unit conversion for viscosity from cSt to cP is accomplished by multiplying viscosity of polysorbate-80 in cSt by its density in g/mL). The method disclosed by McMahon et al. differs from the claimed invention in that McMahon et al. do not disclose the steps of conducting the experiment in an array format. McMahon et al. also do not disclose the step of dispensing less than 250 microliters of the excipient using a positive displacement pump.

Lee et al. disclose an apparatus for conducting solubility tests (see [0005]). The apparatus comprises a microplate 12 (see [0047]), and a positive displacement pump (see [0039]) capable of dispensing 2-10 microliters of highly viscous liquid into the wells of the microplate (see [0067]-[0068]). In light of the disclosure of Lee et al., it would have been obvious to one of ordinary skill in the art to conduct the solubility test disclosed by McMahon et al. using the apparatus disclosed by Lee et al. The apparatus disclosed by Lee et al. would optimize the organization as well as the efficiency of the solubility test.

Although neither McMahon et al. nor Lee et al. explicitly disclose the step of ranking the compounds based on solubility, it would have been obvious to one of ordinary skill in the art to do so once all the samples have been tested. Organizing test

data according to increasing or decreasing value is within the skill of one of ordinary skill in the art.

With regards to claim 20, neither McMahon et al. nor Lee et al. explicitly disclose that degraded or decomposed samples are thrown out from the experiment. Nonetheless, it would have been obvious to one of ordinary skill in the art to selectively exclude decomposed or degraded samples to prevent skewed data caused by defective samples.

With respect to claim 21, it would have been obvious to one of ordinary skill in the art to expand the range of parameters (e.g. concentration of excipient, type of excipient) in the method disclosed by McMahon et al. such that more than 94 samples are prepared so that a more thorough data can be obtained.

Response to Arguments

Applicant's arguments with respect to the art rejection have been fully considered but they are not persuasive.

Applicant argues that McMahon et al. do not disclose a method for conducting high-throughput screening of liquid formulations. This argument is not persuasive. Lines 29-34 of column 17 of the reference disclose a method for conducting a solubility test of the compound “A1” in various excipients (see also Tables 4 and 5). Tables 4 and 5 show that the solubility test of A1 was carried out for 35 different excipients. If the claimed invention constitutes a high-throughput method for screening compositions, then the solubility test disclosed by McMahon et al. also constitutes a high-throughput method for screening compositions. In terms of what constitutes "high-throughput"

according to the claim language, the method requires at least two samples, wherein each sample differs with respect to the liquid excipient or the amount of the compound-of-interest. The test disclosed by McMahon et al. is within the scope of the claim language.

Applicant also argues that Lee et al. do not disclose a method for conducting high-throughput method for screening large numbers of formulations. Specifically, Applicant argues that it would be a mischaracterization to assert that the apparatus disclosed by Lee et al. is designed to conduct solubility testing. This argument is not persuasive. Although the reference does not explicitly disclose a method for conducting solubility tests using the invention, the reference does disclose the existence of the need in the industry to conduct high-throughput solubility tests and that the disclosed apparatus satisfies this need (see [0005]). Based on the disclosure, there is sufficient motivation to conduct solubility tests, including the one disclosed by McMahon et al., using the apparatus disclosed by Lee et al.

For the foregoing reasons, the art rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL S. HYUN whose telephone number is (571)272-8559. The examiner can normally be reached on Monday-Friday 8AM-4:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul S Hyun/
Examiner, Art Unit 1797

/Jill Warden/
Supervisory Patent Examiner, Art Unit 1797